

[illegible]

Group Art Unit: 1644

Attorney  
Docket: 01/21885

**For: A COMPOSITION FOR THE  
PREVENTION AND/OR  
TREATMENT OF  
ATHEROSCLEROSIS**

Attorney  
Docket: 01/21885

## DECLARATION OF PROF. DROR HARATS UNDER 37 CFR 1.132

My research focuses on atherosclerosis. Since the beginning of my career, I have published over 80 scientific articles in highly regarded journals and books, and have presented my achievements at many international

scientific conferences.

I am also a member of The International Society for Atherosclerosis and The European Atherosclerosis Society and the American Heart Association, and was recognized in 1995 a “Young Leading Investigator” both by the International Society of “Drug Affecting Lipid Metabolism” and the “Yoshida Heart Institute” in Japan. I have also served as consultant, collaborator and board member for numerous pharmaceutical and biotechnology companies in Israel, the USA and Europe.

I am a co-inventor of the subject matter described and claimed in the above-referenced U.S. Patent Application.

I have read the Official Actions issued with respect to the above-identified application.

The Examiner has stated that the present invention of a composition for an immunological oral-tolerance inducing composition for the prevention and/or treatment of atherosclerosis is anticipated by, and would have been obvious to one of ordinary skill in the art in view of the referenced prior art. I am of the opinion that the prior art does not anticipate, nor provides motivation for one of ordinary skill in the art to combine the teachings of Strober et al. with Hansson et al., Resch et al. and Sima, et al., and that the scope and content of the prior art, which discloses a method for enhancement of oral tolerance to autoimmune diseases (Strober et al.) and the presence of anti-oxidized LDL antibodies in atherosclerosis (Hansson et al., Resch et al. and Sima et al.) are greatly distinguished from and dissimilar to the present invention.

The present invention is of a unique oral-tolerance inducing composition which is not only novel and nonobvious, but provides an unexpected and previously unavailable basis for prevention and/or treatment of atherosclerosis, and as such responds to a long-felt need in the field of cardiology and preventive medicine.

Strober et al. teaches enhancing oral tolerance to an antigen by suppressing the proinflammatory cytokine IL-12, specifically for the treatment of autoimmune disease. As discussed in detail in the accompanying response to Official Action, atherosclerosis is primarily a disease of deranged lipid metabolism, which does not exhibit the hallmark flare and remission of autoimmune disease, does not respond to conventional immune suppression, and is therefore not commonly classified as an autoimmune disease. Thus, although Hansson et al., Resch et al. and Sima, et al. do teach the presence of anti-oxidized LDL antibodies in atherosclerosis, the significance of Ox LDL to the pathogenesis of atherosclerosis, at the time the invention was made, remained unclear and controversial. For example, in contrast to classic response to autoantigens, it was well known in the art that OxLDL can induce atherosclerosis, while anti-OxLDL antibodies conferred partial protection. Further confounding understanding of the role of OxLDL and potential therapeutic applications is the often-repeated fact of regular dietary intake of significant amounts of OxLDL in cooked animal products.

Applicant has submitted a series of drawings, illustrating the possible effects of oral administration of an antigen on progression of atherosclerosis. As detailed in the accompanying response, and hereinabove, the illustrations depict the inability to infer, without extensive experimentation, which formulations, doses or regimen of treatment will result in induction of oral tolerance (hyporesponsiveness, Panel I, and Oral Tolerance, Panel II), and, on the other hand, which will further stimulate inflammatory response of the gut associated lymph tissue (GALT) (hyperresponsiveness, Panel II), exacerbating disease. One example of such inflammatory immune response to oral feeding of a well known autoantigen is described in Blanas E, et al. (Science 1996;274:1710, enclosed herewith).

Among the criteria applied to determine non-obviousness of an invention is demonstration of unexpected results. While reducing the present invention to practice, employing the methodology disclosed in the instant

specification, we have unexpectedly uncovered further aspects of the prevention and/or treatment of atherosclerosis by oral feeding with Ox LDL, strengthening this unique and novel approach to the disease.

Specifically, in one experiment a dose-dependent reduction in atherosclerotic lesions in genetically susceptible (LDL-RD and Apo-E “knock out”) mice was observed following oral administration of Ox LDL according to the methods of the present invention, thus further confirming the range of “therapeutically effective amount” disclosed in the instant specification. Within the range of 10-1000  $\mu\text{g}$  per mouse, the strongest effect on atherogenesis (45 % reduction in lesions) was observed at a dose of 100  $\mu\text{g}/\text{mouse}$ . In another important series of experiments, a significant, dose-dependent reduction of T-cell proliferation in lymph nodes of LDL-RD and Apo-E “knock out” mice following oral administration of Ox LDL according to the methods of the present invention was observed. Whereas oral administration of as little as 10  $\mu\text{g}/\text{mouse}$  Ox LDL produced a 49 % inhibition of proliferation of Ox LDL-responsive lymphocytes, indicating the ability of orally administered Ox LDL to induce tolerance by clonal anergy/deletion of specific lymphocyte populations. In yet a further series of experiments, immune tissue-specific suppression of the pro-inflammatory cytokine  $\text{INF}\gamma$ , and induction of the anti-inflammatory, Th-2 specific cytokine IL-10 were observed in LDL-RD and Apo-E “knock out” mice following oral administration of Ox LDL according to the methods of the present invention. Such a demonstration of immune modulation by oral administration of Ox LDL now provides the basis for determining therapeutically effective compositions and doses of Ox LDL of the present invention.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment, or both, under Section 1001 of Title 18 of the United states Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

November 21, 2002

A handwritten signature in dark ink, appearing to read "D. Harats", is written over a horizontal line.

Prof. Dror Harats

***Enc.:***

CV of Prof. Dror Harats

Drawings illustrating GALT Immune Response: Panel I and Panel II

Copy of Blanas, E et al. Science 1996;274:1710.

**CURRICULUM VITAE**

**Name:** Dror Harats M.D. **Identity No.:** 5449664-1

**Place of work:** The Sheba Medical Center **Phone No.:** (03)5302940  
Tel Hashomer, 52621

**Faculty/Hospital:** The Sheba Medical Center **Department:** The Institute  
Tel Hashomer, 52621 of Lipid and Atherosclerosis  
Research.

**Home Address:** 71 Mendes St., Ramat-Gan **Phone No.:** (03)5357650

**Date & Place of Birth:** 17/7/56 Israel

**ZAHAL Military Service:** Enlisted: February, 1982.  
Discharged: February, 1985.

**Marital Status:** married **No. of Children:** 2

**A. EDUCATION**

| <b><u>Period of Study</u></b> | <b><u>Name of University</u></b>                                    | <b><u>Subject</u></b> | <b><u>Degree</u></b> | <b><u>Date</u></b> |
|-------------------------------|---|-----------------------|----------------------|--------------------|
| 1974-1981                     | Hebrew University-Hadassah<br>Medical School,<br>Jerusalem, Israel. | Medicine              | M.D.                 | 1982               |

**Specialization Certificate:** Internal Medicine: (1989)  
Pulmonary Medicine: (1995)

**M.D., Thesis:** Non-Invasive Evaluation of Complete Left  
Bundle Branch Block, 1982.

**Name of Supervisor:** Prof. Alexander Batler, Sackler Faculty of  
Medicine, Tel Aviv University.

**B. FURTHER STUDIES**

| <u>Period of Study</u> | <u>Name of University</u>                                      | <u>Subject &amp; Degree</u>                           | <u>Date</u> |
|------------------------|--|---|-------------|
| 1985-1989              | Hebrew University-Hadassah Medical School, Jerusalem, Israel.  | Specialization in internal Medicine.                  | 1989        |
| 1991-1994              | The University of California San Francisco San Francisco, USA. | Specialization in Pulmonary & Critical Care Medicine. | 1994        |
| 1992-1994              | The University of California San Francisco San Francisco, USA. | Postdoctorate Molecular Genetics.                     | 1994        |

**C. ACADEMIC EXPERIENCE**

| <u>Period</u> | <u>Name of Institution</u>                                    | <u>Department</u>                                | <u>Rank/Function</u>          |
|---------------|---|--|-------------------------------|
| 2001-         | Sheba Medical Center Tel-Hashomer, Israel.                    | Basic Research Committee                         | member of the committee       |
| 1999-         | Sackler School of Med., Tel Aviv University, Israel           | Internal Medicine                                | Associate Professor           |
| 1998-         | Sheba Medical Center Tel-Hashomer, Israel.                    | Helsinki- IRB Committee                          | Head of the committee         |
| 1996-         | Sheba Medical Center Tel-Hashomer, Israel.                    | Institute of Lipid and Atherosclerosis Research. | Head of the Institute         |
| 1995-1999     | Sackler School of Med., Tel Aviv University, Israel           | Internal Medicine                                | Senior lecturer               |
| 1994-1996     | Sheba Medical Center Tel-Hashomer, Israel.                    | Institute of Lipid And Atherosclerosis Research. | Senior Scientist & Physician. |
| 1992-1994     | Syntex Discovery Research Palo-Alto, California, USA.         | Molecular Genetics.                              | Visiting Scientist            |
| 1991-1994     | The University of Ca. San Francisco, USA.                     | Cardiovascular Research Institute.               | Postdoctorate                 |
| 1990-1995     | Hebrew University Hadassah Medical School, Jerusalem, Israel. | Internal Medicine                                | Lecturer                      |
| 1987-1990     | Hebrew University Hadassah Medical School, Jerusalem, Israel. | Internal Medicine                                | Instructor                    |

**D. CLINICAL EXPERIENCE**

| <b><u>Period</u></b> | <b><u>Name of Institution</u></b>                                    | <b><u>Department</u></b>                               | <b><u>Rank/Function</u></b> |
|----------------------|--|--|-----------------------------|
| 1996-                | Sheba Medical Center<br>Tel-Hashomer, Israel.                        | Institute of Lipid<br>And Atherosclerosis<br>Research. | Head of the Institute       |
| 1994-1996            | Sheba Medical Center<br>Tel-Hashomer, Israel.                        | Institute of Lipid<br>And Atherosclerosis<br>Research. | Attending Physician         |
| 1994-                | Sheba Medical Center<br>Tel-Hashomer, Israel.                        | Institute of<br>Pulmonary Medicine.                    | Attending Physician         |
| 1991-1994            | The University of<br>California San Francisco<br>San Francisco, USA. | Pulmonary &<br>Critical Care<br>Medicine               | Fellow                      |
| 1989-1991            | Hebrew University<br>Hadassah Medical School,<br>Jerusalem, Israel.  | Internal Medicine                                      | Attending Physician         |
| 1987-1991            | Ministry of Defense.   | Rehabilitation   | District Physician.         |
| 1985-1989            | Hebrew University<br>Hadassah Medical School,<br>Jerusalem, Israel.  | Internal Medicine                                      | Resident                    |
| 1982-1985            | ZAHAL  | The Medical Forces                                     | Captain                     |
| 1981-1982            | Sheba Medical Center<br>Tel Hashomer, Israel.                        | Rotating Internship                                    | Intern                      |



**Boards & Licenses**

VQE-ECFMG, 1981.  
 ECFMG #328-876-8, 1981.  
 Israel, Medical License #017264, 1984.  
 Israel-Boards of Internal Medicine, part 1 & 2, with distinction, 1988 & 1989.  
 Internal Medicine #10791, 1989.  
 FLEX #000088768 part 1 and 2, 1993.  
 Nebraska, license to practice medicine #19509, 1994.  
 Israel-Board in Pulmonary Medicine, part 1 & 2, 1995.

**E. ACADEMIC & PROFESSIONAL AWARDS****Prizes**

|           |  |  |         |
|-----------|--|--|---------|
| 1975      | Hebrew University-Hadassah Medical School                          | "Excellency in Anatomy"  | \$2,000 |
| 1975-1980 | Hebrew University-Hadassah Medical School                          | "Excellence in Studies". (Each year)   | \$3,000 |
| 1988      | Hebrew University-Hadassah Medical School                          | <b>Faculty-Prize</b> for Research "Preferential metabolism by (Sole and Goldberg prize): macrophages of conditioned rabbit hypercholesterolemic remnant lipoproteins." | \$3,000 |
| 1989      |  | Award for <b>Outstanding lecturer.</b>   |         |
| 1990      | Hebrew University-Hadassah Medical School (Dr. M. Sherwood prize): | <b>Faculty-Prize</b> for Research "Cigarette smoking render LDL susceptible to peroxidative modification and enhanced metabolism by macrophages."                      | \$4,000 |
| 1995      | Giovanni Lorenzini Medical Foundation                              | <b>Young Investigator Award,</b> Targeting gene expression to the vascular wall in transgenic mice using the murine preproendothelin-1 promoter                        | \$2,000 |
| 1995      | Sheba Medical Center Tel-Hashomer, Israel.                         | "El-Zohar" Research Prize  | \$4,000 |

**E. ACADEMIC & PROFESSIONAL AWARDS (cont.)****Prizes**

|      |  |   |            |
|------|--|---|------------|
| 1996 | Uchida International Award<br>Japan Foundation of<br>Cardiovascular Research | <b>Young Investigator Award,</b><br>Targeting gene expression to<br>the vascular wall in transgenic<br>mice using the murine<br>preproendothelin-1 promoter | ¥1,000,000 |
|------|--|---|------------|

**Fellowships**

|      |   |   |          |
|------|---|---|----------|
| 1979 | Albert Einstein College of<br>Medicine New York, NY, USA.         | Fellowship Prize.                             | \$3,500  |
| 1991 | Israel Medical Association.                                       | Fellowship-Prize.                             | \$4,000  |
| 1992 | The University of California San<br>Francisco San Francisco, USA. | “Boehringer Ingelheim”<br>Honorary Fellowship | \$25,000 |

**Grants**

|           |  |   |           |
|-----------|--|---|-----------|
| 1991      | The Israel Academy of<br>Sciences and Humanity           | “Wolfson” grant   | \$20,000  |
| 1992-1994 | NIH  | Fogarty International<br>Fellowship Grant.                          | \$70,000  |
| 1995-1998 | United State-Israel<br>Binational Science<br>Foundation. | Binational Grant<br>“Overexpression of 15LO in<br>Transgenic Mice”. | \$110,000 |
| 1995      | Syntex Discovery Research<br>Palo-Alto, California, USA. | Research Grant in Vascular<br>Biology                               | \$10,000  |
| 1995-1998 | The Ministry of Science and<br>The Arts                  | Tissue Specific Gene<br>Therapy to Neovascular<br>Endothelial Cells | \$40,000  |
| 1996-1997 | Israel Cancer Association                                | Tissue Specific Gene<br>Therapy to Neovascular<br>Tumoral Cells     | \$25,000  |

**E. ACADEMIC & PROFESSIONAL AWARDS (cont.)****Grants**

|           |  |   |           |
|-----------|--|---|-----------|
| 1996-2000 | Mercator Genetics                                      | The "Asthma-Gene" in the Jewish population in Israel  | \$507,000 |
| 1997-1998 | Tiber  | "Overexpression of 15LO in Transgenic Mice".  | \$3000    |
| 1998-2000 | Recanati Medical Foundation                            | Long QT Syndrome: The molecular basis of a new mutation.  | \$22,000  |
| 1998-1999 | MSD Foundation Research Grant                          | Secondary Prevention Study ("HOLEM")  | \$480,000 |
| 1998-1999 | Gotvirt Diabetes Research Fund                         | Israel cohort of Glucose intolerance (Phase 3)  | \$5,000   |
| 1999      | Ministry of Health, Chief Scientists office, Jerusalem | Oral Tolerance in Atherosclerosis   | נ"ש20,000 |
| 2000-2001 | Recanati Medical Foundation                            | Tissue Specific Gene Therapy to Neovascular Tumoral Cells.  | \$25,000  |
| 2000-2001 | Israel Cancer Association                              | Using Preproendothelin promoter to direct pro-apoptotic genes to endothelial cells in tumor angiogenesis. | נ"ש65,000 |
| 1999-2002 | BMS Genetic Research Grant                             | Genetics of COPD  | \$320,000 |
| 2000-2003 | Cardimmune   | Immunomodulation and oral tolerance in atherosclerosis.   | \$240,000 |
| 2001-2002 | Olivia   | The effect of fatty acids composition on atherogenesis.   | \$150,000 |
| 2001-     | Serono   | Soluble LDL Receptor  | \$96,000  |

**E. ACADEMIC & PROFESSIONAL AWARDS (cont.)****Grants**

|           |                  |   |            |
|-----------|------------------|---|------------|
| 2002-     | Nikken-Shohonsha | 9-cis retinoic Acid-Lipid Metabolism & Atherogenesis.   | \$305,000  |
| 2000-2002 | Roche            | Xenical in severe hypertriglyceridemic patients.  | CHF131,200 |
| 2001-2002 | קרן עזבונות      | Using Preproendothelin promoter to direct pro-apoptotic genes to endothelial cells in tumor angiogenesis. | ₪150,000   |

**Academic Awards**

|           |   |  |
|-----------|---|--|
| 1999-     | Sackler School of Medicine, Tel Aviv University, Tel Aviv, Israel | Associate Professor in Internal Medicine |
| 1995-1999 | Sackler School of Medicine, Tel Aviv University, Tel Aviv, Israel | Senior lecturer in Internal Medicine     |
| 1990-1995 | Hebrew University Hadassah Medical School, Jerusalem, Israel.     | Lecturer in Internal Medicine            |
| 1987-1990 | Hebrew University Hadassah Medical School, Jerusalem, Israel.     | Instructor in Internal Medicine          |

**F. MEMBERSHIP IN PROFESSIONAL SOCIETIES**

| <u>Since</u> | <u>Society</u>   | <u>Country</u> |
|--------------|--|----------------|
| 1981         | Israel Medical Association.  | Israel         |
| 1987         | Israel Society for Research, prevention and Treatment of Atherosclerosis |                |
| 1989         | International Atherosclerosis Society.                                   | USA            |
| 1991         | American Lung Association.   | USA            |
| 1991         | American Thoracic Society.   | USA            |
| 1991         | American Clinical of Chest Physicians.                                   | USA            |
| 1992         | American Heart Association.  | USA            |
| 1994         | Israel Society of Pulmonary Medicine.                                    | Israel         |
| 1996         | European Atherosclerosis Society   |                |
| 1996         | International Task Force for prevention and Treatment of Atherosclerosis |                |
| 1998         | Israel Heart Society   | Israel         |
| 1998         | Israel Task Force for prevention and Treatment of Atherosclerosis        | Israel         |
| 2000         | Israel Society of Obesity  | Israel         |

**G. ACTIVE PARTICIPATION IN SCIENTIFIC MEETINGS**

| <b><u>Year</u></b> | <b><u>Name of Meeting</u></b>  | <b><u>Location</u></b> |
|--------------------|--|------------------------|
| 2002               | Irish Angiology Symposium- <b>Invited speaker</b>  | Belfast, Ireland       |
| 2002               | International Symposium on Infection & Atherosclerosis<br><b>Invited speaker</b>                               | Washington DC, USA     |
| 2002               | 6 <sup>th</sup> International Dead sea symposium – <b>Invited speaker</b>                                      | Tel-Aviv, Israel       |
| 2001               | 37 <sup>th</sup> EASD Annual Meeting – <b>Invited speaker</b>  | Glasgow, Scotland      |
| 2001               | International Diabetes and Atherosclerosis Symposium<br>– <b>Invited speaker</b>                               | Troon, Scotland        |
| 2001               | Orphan Nuclear Receptors   | Sunnyvale, CA., USA    |
| 2001               | American Diabetes Association – <b>Invited speaker</b>   | Tempe, Arizona, USA    |
| 2001               | EAS workshop on the Immune System & atherosclerosis<br>- <b>Chairman</b>                                       | Geneva, Switzerland    |
| 2001               | The 7 <sup>th</sup> Annual meeting of the Society for Research,<br>Prevention and Treatment of Atherosclerosis | Eilat, Israel          |
| 2000               | XII <sup>th</sup> International Symposium on Atherosclerosis<br>– <b>Invited speaker</b>                       | Stockholm, Sweden      |
| 2000               | 3 <sup>rd</sup> Annual Meeting of American Society of Gene Therapy   | Colorado, USA          |
| 2000               | 2000 EAS workshop, Low HDL in Cardiovascular diseases  | Istanbul, Turkey       |
| 1999               | 1999 NAASO Annual Meeting  | Charleston, SC, USA    |
| 1999               | Immunological Aspects on Cardiovascular Diseases<br>– <b>Invited speaker</b>                                   | Stockholm, Sweden      |
| 1999               | 46 <sup>th</sup> annual meeting of the Israel Heart Society  | Tel-Aviv, Israel       |
| 1999               | Gordon Research Conferences, Atherosclerosis   | Boston, USA            |
| 1999               | 5 <sup>th</sup> Int. Symposium: Multiple risk factors in<br>cardiovascular disease – <b>Invited speaker</b>    | Venice, Italy          |
| 1999               | 2 <sup>nd</sup> International Congress of Autoimmunity<br><b>Invited speaker</b>                               | Tel Aviv, Israel       |
| 1999               | 71 <sup>th</sup> European Atherosclerosis society – <b>Invited speaker</b>                                     | Athens, Greece         |
| 1999               | 71 <sup>th</sup> Scientific Sessions, American Heart Assoc.  | Dallas, USA            |
| 1998               | The Scientific Meeting of the Society for Research,<br>Prevention & Treatment of Atherosclerosis.              | Ashkelon, Israel       |
| 1998               | 70 <sup>th</sup> European Atherosclerosis society – <b>Invited speaker</b>                                     | Geneva, Switzerland    |
| 1998               | European Heart Society.  | Vienna, Austria        |
| 1998               | The Annual Meeting of the Society for Research,<br>Prevention & Treatment of Atherosclerosis.                  | Eilat, Israel          |
| 1998               | Keystone Symposia on Gene Therapy  | Keystone, USA          |
| 1997               | The 11 <sup>th</sup> International Atherosclerosis Society<br>– <b>Invited speaker</b>                         | Paris, France          |
| 1997               | 70 <sup>th</sup> Scientific Sessions, American Heart Assoc.  | Orlando, USA           |
| 1997               | American Thoracic Society International conf.  | SF, USA                |
| 1997               | Keystone Symposia on Atherosclerosis   | Keystone, USA          |

**G. ACTIVE PARTICIPATION IN SCIENTIFIC MEETINGS (cont.)**

| <b><u>Year</u></b> | <b><u>Name of Meeting</u></b>   | <b><u>Location</u></b> |
|--------------------|---|------------------------|
| 1996               | International Task Force for prevention and Treatment of Atherosclerosis – <b>Invited speaker</b> | Berlin, Germany        |
| 1996               | The Israel Society for Arteriosclerosis Research.   | Jerusalem, Israel      |
| 1996               | 64th European Atherosclerosis society.  | Florence, Italy        |
| 1996               | The Annual Meeting of the Society for Research, Prevention & Treatment of Atherosclerosis.        | Eilat, Israel          |
| 1995               | The Israel Society of Pulmonary Medicine  | Tel Aviv, Israel       |
| 1995               | The Israel Society for Arteriosclerosis Research.   | Tel-Aviv, Israel       |
| 1995               | 68th Scientific Sessio, American Heart Assoc.   | Anahime, USA           |
| 1995               | 9th Inter. Symp; Drug Affecting Lipid Metabolism.   | Huston, USA            |
| 1995               | 68th Scientific Sessions, American Heart Assoc.   | Anaheim, USA           |
| 1995               | 64th European Atherosclerosis society – <b>Invited speaker</b>                                    | Utrecht, Netherlands   |
| 1995               | American Thoracic Society International conf.   | Seattle, USA           |
| 1995               | 5th Rappaport Symposium on Modified Lipo-proteins & Antioxidant in Atherosclerosis.               | Shavei-Zion, Israel    |
| 1995               | FASEB Conference, Experimental Biology – <b>Invited speaker</b>                                   | Atlanta, USA           |
| 1995               | The Annual Meeting of the Society for Research, Prevention & Treatment of Atherosclerosis.        | Eilat, Israel          |
| 1994               | 67th Scientific Sessions, American Heart Assoc.   | Dallas, USA            |
| 1994               | the 9th International Conference on Prostaglandins & Related Compounds.                           | Florence, Italy        |
| 1994               | American Thoracic Society International conf.   | Boston, USA            |
| 1994               | The 5th UCSF Pulmonary Research Meeting.  | Asilomar Ca., USA      |
| 1993               | 66th Scientific Sessions, American Heart Assoc.   | Atlanta, USA           |
| 1993               | American Thoracic Society International conf.   | San Francisco, USA     |
| 1993               | The 4th UCSF Pulmonary Research Meeting.  | Asilomar Ca., USA      |
| 1993               | The Annual AIDS Scientific Meeting.   | San Francisco, USA     |
| 1992               | American Thoracic Society International conf.   | Orlando, USA           |
| 1991               | The 9th international symposium on atherosclerosis.   | Chicago, USA           |
| 1990               | The Israel Society for Arteriosclerosis Research.   | Tel-Aviv, Israel       |
| 1990               | 55th European Atherosclerosis Society.  | Brugge, Germany        |

**STUDENTS SUPERVISED BY CANDIDATE****G.1 M.D. STUDENTS****The Hebrew University Hadassah Medical School Jerusalem.**

1990-1991 Peleg Ben Galim M.D.

**Thesis:** "Lipid peroxides in down's syndrome: A study related to the paucity of atherosclerosis in this condition".

**Sackler School of Medicine Tel Aviv University**

1998 Yoav Keidar M.D. Thesis

**Thesis:** "Effect of Colchicine on Atherosclerosis in LDL-Receptor deficient mice".

1998 Yaniv Sherer M.D. Thesis

**Thesis:** "Magnesium fortification of drinking water and atherosclerosis in LDL-receptor ko mice."

2001 Ayana Dvir M.D. Thesis

**Thesis:** "The effect of Omapatrilat on atherogenesis in a combined atherosclerosis – diabetes mouse model in LDL receptor deficient streptozotocin treated mice".

**G.2 M.Sc. & Ph.D. STUDENTS**

1995-2001 Nira Blum Ph.D.

**Thesis:** "Tissue Specific Gene Therapy to Neovascular Tumoral-Endothelial Cells".

1997-2000 Pnina Keren Ph.D.

**Thesis:** "Diabetes in Transgenic Mouse Model of Atherosclerosis".  
*Graduate Cum Laude*

1997-1999 Einat Golan M.Sc.

**Thesis:** "Regulation of LDL-Receptor Expression in Lovastatin Resistant Cells".

1998- Yariv Gerber Ph.D.

**Thesis:** " Apo CII, CIII, TG & Atherosclerotic Cardiovascular Diseases"

1998- Ayelet Gonen M.Sc.

**Thesis:** " Adenoviral Gene Therapy to Neovascular Tumoral-Endothelial Cells"

1998- Grinberger Shoshi MD Ph.D.

**Thesis:** " Induction of Apoptosis in Endothelial Cells"

## **G.2 M.Sc. & Ph.D. STUDENTS (cont.)**

- 1999-  
**Thesis:** Keren Levanon MD/Ph.D.  
"Adenoviral Gene Therapy for Induction of Angiogenesis and vessel maturation."
- 2001-  
**Thesis:** Ayelet Gonen Ph.D.  
"The effect of Allicin derivatives on atherosclerosis mode of actions."
- 2001-  
**Thesis:** Israel Hodish MD Ph.D.  
"Engineering of adeno-viral vector containing the HSV-TK gene under the control of murine pre-proendothelin promoter for the treatment of cancer".

## **G.3 Resident's basic science projects supervised by candidate**

- 1999  
**Thesis:** Arnon Afek Basic-science  
"Anti-HSP65-antibodies and atherosclerosis in LDL-Receptor deficient mice".
- 1998  
**Thesis:** Rafael Bitzur Basic science  
"Induction of IDDM in Transgenic Mouse Model of Atherosclerosis".
- 1997  
**Thesis:** Jakob George Basic-science  
"Anti-phospholipids-antibodies and atherosclerosis in LDL-Receptor deficient mice".
- 1997  
**Thesis:** Peer Dar Zitser Basic-science  
"15 Lipxygenase overexpression reduces fertility in Tg mice".
- 1999  
**Thesis:** Svetlana Poyarovski Basic-science  
"חקר הגנטיקה של COPD בשושלת יוחסין מבודדת בישראל."
- 1999  
**Thesis:** Eyal Leibovitz Basic-science  
"The Association between the polymorphism of the human Paraaxonase gene with plasma Paraaxonase activity and coronary artery disease in Israeli Jewish population."



**G.3 Resident's basic science projects supervised by candidate (cont.)**

|                                    |  |
|------------------------------------|--|
| 1999<br><b><u>Thesis:</u></b>      | Lea Hananashvili      Basic-science<br>"Efficacy of the combination of Fibrates and 9 cis Retinoic Acid on the lipid profile of human Apo A1 transgenic mice".   |
| 2000<br><b><u>Thesis:</u></b>      | Roy Ilan      Basic-science<br>"Amplification of gene expression in transfected cardiomyocytes by ultrasound."   |
| 2000<br><b><u>Thesis:</u></b>      | Levi Zohar      Basic-science<br>"The effect of the natural isomer mixture of $\beta$ -carotene from the alga Dunaliella on the degree and extent of atherosclerosis in apo E deficient mice."         |
| 2000-2001<br><b><u>Thesis:</u></b> | Swetlana Trastman      Basic-science<br>"The effect of the cytokine interferon- $\alpha$ on the degree of atherosclerosis in LDL receptor deficient mice".   |
| 2001<br><b><u>Thesis:</u></b>      | Afek Limor      Basic-science<br>"Oral Tolerance to ox-LDL in LDL-Receptor deficient mice."  |
| 2001<br><b><u>Thesis:</u></b>      | Vladimir Chesnin      Basic-science<br>"Plasma levels and distribution of CII and CIII apolipoproteins: Are they risk factors for Alzheimer's disease?"  |
| 1999-2000<br><b><u>Thesis:</u></b> | Hagith Yonath      Basic-science<br>"Inter-individual variability in sensitivity to warfarin – nature or nurture?"   |
| 2001<br><b><u>Thesis:</u></b>      | Marunich Anastasya      Basic-science<br>"The effect of the natural isomer mixture of $\beta$ -carotene from the alga Dunaliella on the degree and extent of atherosclerosis in apo E deficient mice." |

## **TEACHING EXPERIENCE**

### **Hebrew University Hadassah Medical School, 1988-1991.**

Teaching activities before my departure to the USA.

- 1990            Coordinator of a course in internal medicine for 6th year medical students.
- 1990-1989    Coordinator of the course in cardiopulmonary resuscitation for 6th year medical students.
- 1988-1991    Coordinator of the course in internal medicine for Biotechnicians at the Hadassah College.
- 1989           Award for Outstanding lecturer at the Hebrew University Hadassah Medical School.
- 1988-1991    Teaching internal medicine to 4th year medical students.
- 1990-1991    Supervising an M.D. thesis work at the Hebrew University Hadassah Medical School. "Lipid peroxides in down's syndrome: A study related to the paucity of atherosclerosis in this condition."
- 1990-1991    Member in the Hebrew University Hadassah Medical School. Committee, interviewing candidates for medical school.
- 1990-1991    Teaching in the course of medicine to the new emigrants MDs from the USSR, at the Hebrew University Hadassah Medical School.
- 1991           Preparing the Boards in Internal Medicine for Medical Graduate at the Hebrew University Hadassah Medical School.

### **Sackler Faculty of Medicine, Tel Aviv University, 1995.**

I returned to Israel from the USA in December 1994, since than I am involve in the following teaching activities.

- 1998- 2002    Member of the Medical School Teaching Committee (ועדת הוראה)
- 1998- 2001    Organizing the "Basic Science Correlate Course".
- 1998- 2000    Member of the Committee for Organizing the Clinical Studies Curriculum
- 1998- 2000    Member of the Committee for Organizing the Basic Studies Curriculum
- 1998- 1999    Head of the subcommittee for teaching facilities in the clinical years.
- 1997- 2002    Teaching in the PostGraduate School of Medicine; "Lipids and Lipoprotein Metabolism."
- 1995- 2002    Teaching in the course of Biochemistry for first and third year medical students; "Lipids and Lipoprotein Metabolism."
- 1995- 2002    Teaching fourth year medical students in the course of Internal Medicine; "Hyperlipidemia & Atherosclerosis."
- 1995- 2002    Teaching fourth year medical students (both the NY and the regular program) in the courses Pulmonary medicine.
- 1995- 2002    Teaching in the "Gene Therapy" course for M.Sc. & Ph.D. students.
- 1995- 2002    Seminars in gene therapy to physicians and researchers at Tel Hashomer.

## LIST OF PUBLICATIONS

### A. Book Written

1. Shoenfeld, Y., Harats, D., Wick, G.  
Atherosclerosis and Autoimmunity.  
Elsevier, 370pp, 2001.

### B.1. Original Article

#### **1. Published**

1. Stein, Y., Halperin, G., Harats, D., Stein, O.  
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Biochim. Biophys. Acta 959: 127-133, 1988.
3. Stein, O., Oette, K., Harats, D., Halperin, G., Stein, Y.  
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4. Stein, O., Harats, D., Schwartz, R., Berry, E. M., Stein, Y.  
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Biochim. Biophys. Acta 1033: 115-120, 1989.
5. Harats, D., Ben-Naim, M., Dabach, Y., Hollander, G., Stein, O., Stein, Y.  
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6. Harats, D., Raz, I., Lebensart, P.  
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Isr. J. Med. Sci. 26: 168-170, 1990.
7. Harats, D., Ben-Naim, M., Dabach, Y., Hollander, G., Havivi, E., Stein, O., Stein, Y.  
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Effects of diets rich in monounsaturated fatty acids on plasma lipoproteins - The Jerusalem Nutrition Study: high MUFAs vs high PUFAs.

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9. Harats, D., Dabach, Y., Hollander, G., Ben-Naim, M., Schwartz, R., Berry, E. M., Stein, O., Stein, Y.

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10. Berry, E. M., Eisenberg, S., Friedlander, Y., Harats, D., Kaufmann, N., Norman, Y., Stein, Y.

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Am. J. Clin. Nutr. 56(2): 394-403, 1992.

11. Beigel, Y., Brook, G., Eisenberg, S., Fainaru, MS., Harats, D., Levy, Y., Rubinstein, A., Skurnik, Y.

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Isr. J. Med. Sci. 29 (5): 272-277, 1993.

12. Harats, D., Mulkin, M.A., Sigal, E.

A possible role for 15-lipoxygenase in atherosclerosis.

Trends in Cardiovascular Medicine. 5(1): 29-36, 1995.

13. Harats, D., Kurihara, H., Belloni, P., Oakley, H., Ziober, A., Ackley, D., Cain, G., Kurihara, Y., Lawn, R., Sigal, E.

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14. Berry, E. M., Eisenberg, S., Friedlander, Y., Harats, D., Kaufmann, N., Norman, Y., Stein, Y.

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16. D. Harats., Chevion, S., Nahir, M., Norman, Y., Sagee, O., Berry, ME.  
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18. George, J., Afek, A., Gillburd, B., Blank, M. Levy, Y., Aron-Maor, A., Levkovitz, H., Shaish, A., Goldberg, I., Kopolovic, J., Harats, D., Shoenfeld, Y.  
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19. George, J., Gilburd, B., Langevitz, P., Levy, Y., Nezlín, R., Harats, D., Shoenfeld, Y.  
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20. Afek, A., George, J., Shoenfeld, Y., Gillburd, B., Levi, Y., Shaish, A., Keren, P., Goldberg, I., Kopolovic, J., and Harats, D.  
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21. George, J., Shoenfeld, Y., Afek, A., Gillburd, B., Keren, P., Shaish, A., Kopolovitz, Y., Wick, G., and Harats, D.  
"Enhanced fatty streak formation in C57BL/6 mice by immunization with heat-shock protein 65"  
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23. **George, J\*., Harats, D\*.**, Gillburd, B., Afek, A., Levy, Y., Shneiderman, J.,  
Koplovic, J., Shoenfeld, Y.  
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**\*Both are first authors**

24. George, J., Aron, A., Levi, Y., Ben-David, A., Hojnik, M., Renaudineau, Y., Zonana-  
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32. George, J., Mulkins, M., Casey, S., Schatzman, R., Sigal, E., Harats, D.

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33. George J., Ahmed A., Patnaik M., Adler Y., Levy Y., Harats D., Gilburd B., Terryberry J., Qui Shen G., Sagie A., Herz I., Snow P., Brandt J., Peter J., Shoenfeld Y.

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34. Sherer, Y., Shaish, A., Levkovitz, H., Keren, P., Janackovic, Z., Shoenfeld, Y., Harats, D.

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35. Knoblauch, H., Muller-Myhsok, B., Busjahn, A., Ben Avi, L., Bähring, S., Baron, H., Heath, SC., Uhlmann, R., Faulhaber, HD., Shpitzen, S., Aydin, A., Reshef, A., Rosenthal, M., Eliav, O., Muhl, A., Lowe, A., Schurr, D., Harats, D., Jeschke, E., Friedlander, Y., Schuster, H., Luft, FC., Leitersdorf, E.

A cholesterol-lowering gene maps to chromosome 13Q.

The American J. of Human Genetics 66(1):157-66, 2000.

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36. Afek, A., George, J., Gilburd, B., Rauova, L., Goldberg, I., Kopolovic, J., Harats, D., Shoenfeld, Y.

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J Autoimmun. 14(2):115-121, 2000.

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37. Jacob George, Mary Mulkins, Aviv Shaish, Sharon Casey, Randall Schatzman, Elliott Sigal, Dror Harats.

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Atherosclerosis 153:403-411, 2000.

38. Dror Harats, Aviv Shaish, Jacob George, Mary Mulkins, Hiroki Kurihara, Hana Levkovitz and Elliott Sigal.

Overexpression of 15-Lipoxygenase in the Vascular Endothelium Accelerates Early Atherosclerosis in LDL Receptor-Deficient Mice.

Arteriosclerosis, Thrombosis and Vascular Biology 20(9):2100-5, 2000.

39. Pnina Keren, Jacob George, Aviv Shaish, Hana Levkovitz, Zora Janakovic, Arnon Afek, Iris Goldberg, Juri Kopolovic, Gad Keren, Dror Harats.

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40. Sherer Y, Shoenfeld Y, Shaish A, Levkovitz H, Bitzur R, Harats D.

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Pathobiology 68:93-98, 2000.

41. Halperin G, Elisaf M, Leitersdorf E and Harats D.

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42. J. George, P-L. Meroni, B. Gilburd, E. Raschi, D. Harats and Y. Shoenfeld.

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43. J. George, Y. Shoenfeld, B. Gilburd, A. Afek, A. Shaish and D. Harats.  
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44. **J. George\*** **D. Harats\***, B. Gilburd, A. Afek, A. Shaish, J. Kopolovic, and Y.  
Shoenfeld.  
Adoptive transfer of  $\beta$ 2 glycoprotein I ( $\beta$ 2GPI)-reactive lymphocytes enhances early  
atherosclerosis in LDL receptor deficient mice.  
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**\*Both are first authors**

45. J. George, A. Afek, B. Gilburd, Y. Shoenfeld and D. Harats  
Cellular and Humoral Immune response to HSP 65 are both involved in promoting fatty-  
streak formation in LDL-receptor deficient mice.  
JACC 38(3):900-905, 2001.

46. Y. Sherer, A. Tenenbaum, M. Blank, J. Shemesh, D. Harats, E.Z. Fisman, S.  
Praprotnik, M. Motro, Y. Shoenfeld.  
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Amr J. Hypertension. 14:149-154, 2001.

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Praprotnik, M. Motro, Y. Shoenfeld  
Coronary Calcium and Anti-Cardiolipin Antibody are elevated in patients with Typical  
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The ubiquitin-proteasome pathway mediates the regulated degradation of mammalian  
HMG-CoA reductase.  
J Biol Chem. 275:35840-35847, 2000.

49. Pnina Keren, Jacob George, Gad Keren, Dror Harats.  
Non-Obese Diabetic (NOD) mice exhibit an increased cellular immune response to  
glycated-LDL but are resistant to high fat diet induced atherosclerosis  
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The effect of renin-angiotensin-axis inhibition on atherogenesis in LDL-receptor deficient mice.  
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53. Yehuda Shoenfeld, Yaniv Sherer, Jacob George and Dror Harats.  
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54. Y. Sherer, R. Bitzur, H. Cohen, A. Shaish, D. varon, Y. Shoenfeld, D. Harats.  
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55. N. Varda-Bloom, A. Shaish, A. Gonen, K. Levanon, S. Greenbereger, S. Ferber, H. Levkovitz, A. Afek, Y. Kopolovitch, D. Harats.  
Tissue-Specific Gene Therapy Directed to Tumor Angiogenesis.  
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57. J. George, A. Afek, A. Shaish, H. Levkovitz, N. Bloom, T. Cyrus, L. Zhao, C. D. Funk, E. Sigal, D. Harats.  
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Trends Immunol. 22(6): 293-295, 2001.

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15-lipoxygenase.  
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64. E. Leibovitz, D. Harats, D. Gavish.  
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Klin. Wochensch. 67(9): 502-505, 1989.
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The genetics of Hyperlipidemia.

Cardiology Update 10:27-32,1995.

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Emerging Cross-Regulatory Roles of Immunity and Autoimmunity in Atherosclerosis.

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Lupus 9:223-227, 2000.
12. Y. Shoenfeld, D. Harats and J. George  
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### **B.4. Chapters in Books**

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Atherosclerosis: Evidence for the role of autoimmunity.  
In: Atherosclerosis and Autoimmunity; Elsevier, 139-142, 2001.
3. Shere, Y., Blank, M., Varrala, O., Shaish, A., Shoenfeld, Y., Harats, D.  
Anti-prothrombin antibodies in thrombosis and atherosclerosis.  
In: Atherosclerosis and Autoimmunity; Elsevier, 185-190, 2001.
4. Harats, D., Cohen, H.  
טרשת העורקים - הבנה ביולוגית חדשה, מערכת החיסון וסוכרת.  
Atherosclerosis – the immune system and diabetes  
Diabetes Mellitus in the 3<sup>rd</sup> millennium, 117-130, 2001  
סוכרת באלף השלישי, האגודה הישראלית לסוכרת, 2001, 117-130

**D.1. Invited papers in scientific meeting**

1. Stein, O., Harats, D., Stein, Y.

Lipoproteins, smooth muscle cells and macrophages.

In: Proceedings of 8th intl. Symposium Atherosclerosis, Rome, Atherosclerosis VIII, ed. G. Crepaldi, Excerpta Medica: 81-84, 1988.

2. Stein, Y., Halperin, G., Harats, D., Stein, O.

Metabolic fate and effect on cholesterol removal of liposomes prepared from 1,3-di-o-octadecenylglycero-2-phosphocholine studied in vivo and in vitro.

Oncology Overview. 18: October 1989.

3. Sigal, E., Kurihara, H., Belloni, P., Cain, G., Lawn, R., Harats, D.,

Targeting gene expression to the vascular wall in transgenic mice using the murine preproendothelin-1 promoter.

In the proceedings of the 64th European Atherosclerosis Society, Utrecht, Netherlands, S41, 1995.

4. Harats, D., Kurihara, H., Levkovitz, H., Shaish, A., Sigal, E.

15-Lipoxygenase overexpression induces atherosclerosis in LDL -receptor deficient mice.

Circulation (134) 279, 1997.

5. Harats, D.

The immune system in atherogenesis.

In the proceedings of the 4<sup>th</sup> Annual Meeting of the Society for Research, Prevention and Treatment of Atherosclerosis, Eilat, Israel, 1998.

6. Harats, D., George, J., Afek, A., Gillburd, B., Levkovitz, H., Shaish, A., Kopolovitz, Y., Wick, G., Shoenfeld, Y.

Immunomodulation of atherogenesis.

In the proceedings of the 70<sup>th</sup> EAS, Geneva, Switzerland, 1998.

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7. Harats, D., George, J., Gillburd, B., Afek, A., Shaish, A., Shoenfeld, Y.

Beta 2 glycoprotein I (Apolipoprotein-H) as an influential determinant in atherosclerosis.

In the proceedings of the 71<sup>st</sup> ESA congress, Athens, Greece, May 1999.

8. D. Harats, J. George, B. Gilburd, A. Afek, A. Shaish, Y. Shaish.

Adoptive transfer of  $\beta$ 2-glycoprotein I reactive lymphocyte enhances atherosclerosis in LDL receptor deficient mice In the proceedings of the 12<sup>th</sup> ISA, Stockholm, Sweden, 2000.

9. D. Harats.

The Immune system in Atherosclerosis. In the proceedings of the 37<sup>th</sup> EASD, Glasgow, Scotland, 2001.



**D.2. Papers presented at scientific meetings**

1. Harats, D., Stein, O., Stein, Y.  
Cigarette smoking render LDL susceptible to peroxidative modification.  
The Israel Society for Arteriosclerosis Research, Tel-Aviv, March 1990.
2. Stein, Y., Berry, E. M., Eisenberg, S., Harats, D., Friedlander, Y., Norman, Y., Kaufmann, N.  
Effect of dietary mono-vs. polyunsaturated fatty acids on plasma lipoproteins in a free living population.  
The 55th Annual Meeting of the European Atherosclerosis Society, Brugge, May 1990.
3. Eisenberg, S., Berry, E. M., Kaufmann, N., Harats, D., Friedlander, Y., Stein, Y.  
The effect of dietary substitution of monounsaturated fatty acids (MFA) with carbohydrates (CHO) as lipoprotein levels, structure and function in a free living population.  
The 63rd Scientific Sessions, American Heart Assoc., New Orleans, USA, Nov. 1993.
4. Beigel, Y., Levy, Y., Rubinstein, A., Skurnik, Y., Harats, D., Eisenberg, S., Brook, G., Fainaru, M.  
Pravastatin therapy in Israel: Efficacy and safety in moderate hypercholesterolemic patients.  
The 9th international symposium on atherosclerosis, Chicago, October 1991.
5. Berry, E. M., Eisenberg, S., Harats, D., Friedlander, Y., Kaufmann, N., Stein, Y.  
The effects of dietary oleic acid on plasma lipids and their tendency to peroxidation.  
The 9th international symposium on atherosclerosis, Chicago, October 1991.
6. Harats, D., Dabach, Y., Hollander, G., Ben-Naim, M., Schwartz, R., Berry, E. M., Stein, O., Stein, Y.  
Fish oil ingestion in smokers and nonsmokers enhances peroxidation of plasma lipoproteins; attenuating effect of vitamin E  
The 9th international symposium on atherosclerosis, Chicago, October 1991.
7. Harats, D., Sigal, E.  
Directing genes expression to the vascular wall and the airway epithelium in transgenic mice.  
The 4th Pulmonary Research Scientific Meeting, Asilomar Ca. September, 1993.
8. Staler, F., Golden, J., Stansel, J., Harats, D., Montgomery, A.B., Walser, J.  
Aerosolized recombinant human interferon gamma as adjuvant therapy for Pneumocystis Carinii Pneumonia in patients with AIDS.  
The Annual AIDS Scientific Meeting. San Francisco, Ca. October, 1993.

**D.2. Papers presented at scientific meetings (cont.)**

9. Harats, D., Kurihara, H., Belloni, P., Oakley, H., Ziober, A., Ackley, D., Cain, G., Kurihara, Y., Lawn, R., Sigal, E.

Using transgenic mice to investigate *in vivo* biology of lipoxygenases.

The 9th International Conference on Prostaglandins & Related Compounds, Florence, June, 1994.

10. Harats, D., Sigal, E.

Targeting gene expression to the vascular wall in transgenic mice using the murine preproendothelin-1 promoter

The 5th Pulmonary Research Scientific Meeting, Asilomar Ca. September, 1994.

11. Harats, D., Kurihara, H., Belloni, P., Oakley, H., Ziober, A., Cain, G., Kurihara, Y., Lawn, R., Sigal, E.

Targeting gene expression to the vascular wall in transgenic mice using the murine preproendothelin-1 promoter

The 67th Scientific Sessions, American Heart Assoc., Dallas, USA, Nov. 1994.

12. Sigal, E., Kurihara, H., Belloni, P., Cain, G., Lawn, R., Harats, D.

Targeting gene expression to the vascular wall in transgenic mice using the murine preproendothelin-1 promoter.

FASEB Conference, Experimental Biology, Atlanta, USA April 1995.

13. Sigal, E., Kurihara, H., Belloni, P., Cain, G., Lawn, R., Harats, D.,

Targeting gene expression to the vascular wall in transgenic mice using the murine preproendothelin-1 promoter.

64th European Atherosclerosis Society, Utrecht, Netherlands, June, 1995.

14. Harats, D., Kurihara, H., Belloni, P., Oakley, H., Ziober, A., Cain, G., Kurihara, Y., Lawn, R., Sigal, E.

Taexpression to the vascular wall and the airway epithelium in transgenic mice using the murine preproendothelin-1 promoter.

The American Thoracic Society International conf., Seattle, USA, May 1995.

15. Harats, D., Tomlanovich, SJ, Conte, Jr JE, Golden, JA.

Aerosolized pentamidine prophylaxis for *Pneumocystis Carinii Pneumonia* in solid organ transplantation: Preliminary observation.

The 35th ICAAC, September 1995.

16. Harats, D., Kurihara, H., Lawn, R., Sigal, E.

Targeting gene expression to the vascular wall in transgenic mice using the murine preproendothelin-1 promoter.

The 12th Inter. Symp. on Drug Affecting Lipid Metabolism, Houston, Texas, USA. November, 1995.

**D.2. Papers presented at scientific meetings (cont.)****17. Harats, D., Sigal, E.**

Targeting gene expression to the vascular wall in transgenic mice the murine prepromoter.

The Israel Society for Arteriosclerosis Research., Tel Aviv, Israel, December 1995.

**18. Harats, D.,**

Targeting gene expression to the airway epithelium and the vascular wall in transgenic mice using the murine preproendothelin-1 promoter.

The annual meeting of the Israel Society of Pulmonary diseases, Tel Aviv, Israel, December 1995.

**19. Harats, D., Kurihara, H., Levkovitz., Sigal, E.**

15-Lipoxygenase overexpression induces atherosclerosis in LDL deficient mice.

The 66th Annual Meeting of the European Atherosclerosis Society, Florence, Italy July 1996.

**20. Harats, D.,**

15-Lipoxygenase overexpression induces atherosclerosis in LDL deficient mice.

The Israel Society for Arteriosclerosis Research. Jerusalem, Israel, December 1996.

**21. Harats, D., Kurihara, H., Levkovitz., Sigal, E.**

15-Lipoxygenase overexpression induces atherosclerosis in LDL deficient mice.

Keystone Symposia on Atherosclerosis, Keystone, USA 1997.

**22. Harats, D., Kurihara, H., Sigal, E.**

Taexpression to the airway epithelium and the vascular wall in transgenic mice using the murine preproendothelin-1 promoter.

International congress on cilia mucus & mucociliary interactions, Jerusalem, Israel, February 1997.

**23. Harats, D., George, J., Afec, A., Gillburd, B., Levkovitz, H., Shaiah, A., Goldberg, I., Kopolovitz, Y., Shoenfeld, Y.**

Hyperimmunization of chow fed apo-E deficient mice with homologous oxidized Low Density Lipoprotein suppresses early atherogenesis.

XI I.A.S, Paris France 1997

**24. Harats, D., Kurihara, H., Levkovitz, H., Shaiah, A., Sigal, E.**

15-Lipoxygenase overexpression induces atherosclerosis in LDL -receptor deficient mice.

XI I.A.S, Paris France 1997

**D.2. Papers presented at scientific meetings (cont.)**

25. Harats, D., George, J., Afec, A., Gillburd, B., Blank, M., Goldberg, I., Kopolovitz, Y., Wick, G., Shoenfeld, Y.

Accelerated Early Atherogenesis in C57BL/6J Mice Immunized With Mycobacterium Tuberculosis. XI I.A.S, Paris France 1997

26. Shaish, A., George, J., Afec, A., Gillburd, B., Kopolovitz, Y., Shoenfeld, Y., Harats, D.

Induction of early atherosclerosis in LDL-receptor deficient mice immunized with beta 2 glycoprotein I.

XI I.A.S, Paris France 1997

27. Harats, D., Kurihara, H., Shaish, A., Sigal, E.

15-Lipoxygenase overexpression induces atherosclerosis in LDL -receptor deficient mice.

70th Scientific Sessions, American Heart Assoc. Orlando, USA 1997

28. Harats, D., Shaish, A., George, J., Afec, A., Gillburd, B., Kopolovitz, Y., Shoenfeld, Y.

Induction of early atherosclerosis in LDL-receptor deficient mice immunized with beta 2 glycoprotein I.

70th Scientific Sessions, American Heart Assoc. Orlando, USA 1997

29. Ehrenfeld, M., Harats, D.

Serum lipoprotein(a) level in patients with systemic lupus erythematosus.

5<sup>th</sup> International Conference on SLE, Cancun, Mexico 1998

30. Harats, D., Shaiah, A., Levkovitz., Sigal, E., Bloom, VN.

Tissue specific gene therapy to the vascular wall.

Keystone Symposia on Gene-Therapy Keystone, USA 1998.

31. Harats, D.

The immune system in atherogenesis.

The 4<sup>th</sup> Annual Meeting of the Society for Research, Prevention and Treatment of Atherosclerosis, Eilat, Israel, 1998.

32. Harats, D., George, J., Afek, A., Gillburd, B., Levkovitz, H., Shaish, A., Kopolovitz, Y., Wick, G., Shoenfeld, Y.

Immunomodulation of atherogenesis.

70<sup>th</sup> European Atherosclerosis society, Geneva, Switzerland, 1998.

33. Shaish, A., Levkovitz, H., George, J., Gillburd, B., Keren, P., Harats, D.

Antioxidant vitamins do not inhibit atherogenesis in an Apolipoprotein E-deficient mouse model.

70<sup>th</sup> European Atherosclerosis society, Geneva, Switzerland, 1998.

**D.2. Papers presented at scientific meetings (cont.)**

**34.** George, J., Shoenfeld, Y., Afek, A., Gillburd, B., Keren, P., Shaish, A., Kopolovitz, Y., Wick, G., and Harats, D.

“Enhanced fatty streak formation in C57BL/6 mice by immunization with heat-shock protein 65”

70<sup>th</sup> European Atherosclerosis society, Geneva, Switzerland, 1998.

**35.** Bloom, VN., Shaiah, A., Levkovitz., Sigal, E., Harats, D.

Tissue specific gene therapy to the vascular wall.

The Scientific Meeting of the Society for Research, Prevention and Treatment of Atherosclerosis, Ashkelon, Israel, 1998.

**36.** George, J., Shoenfeld, Y., Afek, A., Gillburd, B., Keren, P., Shaish, A., Kopolovitz, Y., Wick, G., and Harats, D.

“Enhanced fatty streak formation in C57BL/6 mice by immunization with heat-shock protein 65”

The Scientific Meeting of the Society for Research, Prevention and Treatment of Atherosclerosis, Ashkelon, Israel, 1998.

**37.** Afek, A., George, J., Gillburd, B., Keren, P., Goldberg, I., Kopolovic, J., Shoenfeld, Y., Harats, D.

Enhancement of atherosclerosis in apo-E deficient mice immunized with beta 2 glycoprotein I.

The Scientific Meeting of the Society for Research, Prevention and Treatment of Atherosclerosis, Ashkelon, Israel, 1998.

**38.** Shaish, A., George, J., Gillburd, B., Keren, P., Levkovitz, H., Harats, D.

Dietary B-carotene and alpha-tocopherol combination dose not inhibit atherogenesis in an Apolipoprotein E-deficient mouse model.

The Scientific Meeting of the Society for Research, Prevention and Treatment of Atherosclerosis, Ashkelon, Israel, 1998.

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**39.** George, J., Harats, D., Afek, A., Gillburd, B., Shaish, A., Shoenfeld, Y.

The Role of Heat Shock Protein 65 (HSP) in Murine Atherosclerosis.

2<sup>nd</sup> International Congress of Autoimmunity, Tel Aviv, Israel, March 1999.

**40.** Harats, D., George, J., Gillburd, B., Afek, A., Shaish, A., Shoenfeld, Y.

$\beta$ 2-Glycoprotein I (Apolipoprotein-H) as an Influential Determinant in Atherosclerosis.

2<sup>nd</sup> International Congress of Autoimmunity, Tel Aviv, Israel, March 1999.

**D.2. Papers presented at scientific meetings (cont.)**

41. Zurgil, N., Levy, Y., Deutsch, M., Gillburd, B., George, J., Harats, D., Kaufman, M., Shoenfeld, Y.

Reactivity of Peripheral Blood Lymphocytes (PBL) to oxLDL: A Novel System to Estimate Atherosclerosis Employing The Cellscan.

2<sup>nd</sup> International Congress of Autoimmunity, Tel Aviv, Israel, March 1999.

42. Harats, D., George, J., Afek, A., Gillburd, B., Shoenfeld, Y.

Administration of beta 2 glycoprotein I reduces atherogenesis in LDL-receptor-deficient mice.

5<sup>th</sup> Int. Symposium: Multiple risk factors in cardiovascular disease, Venice, Italy, October 1999.

43. Leibovitz, E., Gavish, D., Roitelman, Y., Shaish, A., Harats, D.,

The association of GLN-ARG 192 and MET-LEU 54 polymorphism of human paroxonase (PON1) gene with coronary artery disease in Israeli Jewish population.

5<sup>th</sup> Int. Symposium: Multiple risk factors in cardiovascular disease, Venice, Italy, October 1999.

44. Sherer, Y., Shaish, A., Levkovitz, H., Keren, P., Janackovic, Z., Shoenfeld, Y., Harats, D.

Magnesium fortification of drinking water suppresses atherogenesis in male LDL-Receptor knockout mice

46<sup>th</sup> annual meeting of the Israel Heart Society, Tel-Aviv, Israel, April 1999.

45. Keren, P., Shaish, A., Levkovitz, H., Gilbrud, B., Janakovic, Z., Shoenfeld, Y., Harats, D.

Combined hyperlipidemic hyperglycemic model of Atherosclerosis in Apo-E Deficient Mice:

46<sup>th</sup> annual meeting of the Israel Heart Society, Tel-Aviv, Israel, April 1999.

46. Shaish, A., Sherer, Y., Levkovitz, H., Shoenfeld, Y., Harats, D.

Magnesium fortification of drinking water suppresses atherogenesis in male LDL-Receptor knockout mice

71<sup>st</sup> ESA congress, Athens, Greece, May 1999.

47. Keren, P., George, J., Shaish, A., Levkovitz, H., Gilbrud, B., Janakovic, Z., Keren, G., Shoenfeld, Y., Harats, D.

Combined hyperlipidemic hyperglycemic model of Atherosclerosis in Apo-E Deficient Mice:

71<sup>st</sup> ESA congress, Athens, Greece, May 1999.

**D.2. Papers presented at scientific meetings (cont.)**

48. George, J., Harats, D., Gillburd, B., Afek, A., Levy, Y., Shaish, A., Barshak, I., Shneiderman, J., Kopolovic, J., Shoenfeld, Y.  
Immunolocalization of beta 2 glycoprotein I (Apolipoprotein-H) to human atherosclerotic plaques: Potential implication for lesion progression.  
71<sup>st</sup> ESA congress, Athens, Greece, May 1999.
49. Harats, D., George, J., Gillburd, B., Afek, A., Shaish, A., Shoenfeld, Y.  
Beta 2 glycoprotein I (Apolipoprotein-H) as an influential determinant in atherosclerosis.  
71<sup>st</sup> ESA congress, Athens, Greece, May 1999.
50. N. Varda-bloom, A. Shaish, A. Gonen, S. Ferber, H. Levkovitz, D. Harats.  
Vascular Specific Gene Therapy to Tumor Veovascularization.  
3<sup>rd</sup> Annual meeting, American society of gene Therapy, Denver, Colorado, June 2000.
51. P. Keren, A. Shaish, J. George, D. Harats  
The effect of  $\beta$ -carotene and  $\alpha$ -tocopherol supplementation on accelerated atherosclerosis in diabetic apoE deficient mice  
12<sup>th</sup> ISA, Stockholm, Sweden, Vol 151(1), Page 12, 2000.
52. N. Varda-bloom, A. Shaish, A. Gonen, H. Levkovits, D. Harats.  
The PPE1 promoter as a tool for specific gene therapy to angiogenic vascular endothelial cells  
12<sup>th</sup> ISA, Stockholm, Sweden, Vol 151(1), Page 101, 2000.
53. D. Harats, J. George, B. Gilburd, A. Afek, A. Shaish, Y. Shoenfeld.  
Adoptive transfer of  $\beta$ 2-glycoprotein I reactive lymphocyte enhances atherosclerosis in LDL receptor deficient mice  
12<sup>th</sup> ISA, Stockholm, Sweden, Vol 151(1), Page 166, 2000.
54. A. Afek, J. George, Y. Shoenfeld, B. Gilburd, D. Harats.  
Cellular humoral immune responses to HSP 65 are both involved in promoting fatty streak formation in LDL –receptor deficient mice  
12<sup>th</sup> ISA, Stockholm, Sweden, Vol 151(1), Page 189, 2000.
55. A. Shaish, D. Mirelman, D. Abramovitz, T. Miron, A. Rabinkov, M. Wilchek, M. Eldar, Z. Vered, H. Levkovitz, D. Harats  
12<sup>th</sup> ISA, Stockholm, Sweden, Vol 151(1), Page 257, 2000.
56. J. George, Y. Shoenfeld, B. Gilburd, A. Afek, A. Shaish, D. Harats  
A requisite role for IL-4 in the acceleration of fatty streaks induced by HSP65 or mycobacterium tuberculosis  
12<sup>th</sup> ISA, Stockholm, Sweden, Vol 151(1), Page 190, 2000.

**D.2. Papers presented at scientific meetings (cont.)**

57. T. Ravid, R. Doolman, R. Avner, M. Fainaro, D. Harats, J. Roitelman.  
The ubiquitin-proteasome pathway mediates the regulated degradation of mammalian HMG-CoA reductase.  
The 7<sup>th</sup> Annual meeting of the Society for Research, Prevention and Treatment of Atherosclerosis, Eilat, Israel, May 2001.
58. A. Afek, G. Keren, D. Harats, J. George  
Whole body hyperthermia accelerates atherogenesis in low density lipoprotein receptor deficient mice.  
The 7<sup>th</sup> Annual meeting of the Society for Research, Prevention and Treatment of Atherosclerosis, Eilat, Israel, May 2001.
59. Z. Levy, A. Shaish, N. Yacov, H. Levkovitz, S. Trestman, Y. Gerber, H. Cohen, R. Rhachmani, D. Harats  
Rosiglitazone attenuate atherogenesis with no effect on hyperglycemia in a combined diabetes-atherosclerosis mouse model.  
The 7<sup>th</sup> Annual meeting of the Society for Research, Prevention and Treatment of Atherosclerosis, Eilat, Israel, May 2001.
60. H. Cohen, Y. Sherer, A. Shaish, H. Levkovitz, R. Bitzur, Y. Shoenfeld, D. Harats  
Rosiglitazone attenuate atherogenesis with no effect on hyperglycemia in a combined diabetes-atherosclerosis mouse model.  
The 7<sup>th</sup> Annual meeting of the Society for Research, Prevention and Treatment of Atherosclerosis, Eilat, Israel, May 2001.
61. D. Harats, J. George, Y. Shoenfeld.  
Autoantigens in Atherogenesis  
The EAS workshop on the Immune System & atherosclerosis. Geneva, Switzerland March 2001.
62. D. Harats.  
The Immune system in Atherosclerosis.  
The 37<sup>th</sup> Annual meeting of the EASD, Glasgow, Scotland, September 2001.
63. D. Harats.  
The Immune system, Atherosclerosis and Diabetes.  
The International Diabetes and Atherosclerosis Symp. Troon, Scotland, September 2001.
64. D. Harats.  
The Immune system, Atherosclerosis and Diabetes.  
The American Diabetes Association Workshop, Tempe, Arizona, USA, September 2001.
65. D. Harats. The immune system in cardiovascular disease.  
The 6<sup>th</sup> International Dead sea symposium. Tel-Aviv, Israel, March 2002



### **D.3. Abstracts and Proceedings.**

#### **1. Published**

1. Stein, Y., Halperin, G., Harats, D., Stein, O.  
Metabolic fate and effect on cholesterol removal of liposomes prepared from 1,3-di-o-octadecenylglycero-2-phosphocholine studied in vivo and in vitro.  
Oncology Overview. 18: October 1989.
2. Stein, Y., Berry, E. M., Eisenberg, S., Harats, D., Friedlander, Y., Norman, Y., Kaufmann, N.  
Effect of dietary mono-vs. polyunsaturated fatty acids on plasma lipoproteins in a free living population.  
In: Proceedings of the 55th Annual European Atherosclerosis Society Meeting, May 1990.
3. Eisenberg, S., Berry, E. M., Kaufmann, N., Harats, D., Friedlander, Y., Stein, Y.  
The effect of dietary substitution of monounsaturated fatty acids (MFA) with carbohydrates (CHO) as lipoprotein levels, structure and function in a free living population.  
Circulation , Supplement III. 82:4, 474, 1990.
4. Beigel, Y., Levy, Y., Rubinstein, A., Skurnik, Y., Harats, D., Eisenberg, S., Brook, G., Fainaru, M.  
Pravastatin therapy in Israel: Efficacy and safety in moderate hypercholesterolemic patients.  
In: Proceedings of the 9th international symposium on atherosclerosis, 48 October, 1991.
5. Berry, E. M., Eisenberg, S., Harats, D., Friedlander, Y., Kaufmann, N., Stein, Y.  
The effects of dietary oleic acid on plasma lipids and their tendency to peroxidation.  
In: Proceedings of the 9th international symposium on atherosclerosis, 92 October, 1991.
6. Harats, D., Dabach, Y., Hollander, G., Ben-Naim, M., Schwartz, R., Berry, E. M., Stein, O., Stein, Y.  
Fish oil ingestion in smokers and nonsmokers enhances peroxidation of plasma lipoproteins; attenuating effect of vitamin E  
In: Proceedings of the 9th international symposium on atherosclerosis, 144 October, 1991.
7. Harats, D., Kurihara, H., Belloni, P., Oakley, H., Ziober, A., Ackley, D., Cain, G., Kurihara, Y., Lawn, R., Sigal, E.  
Using transgenic mice to investigate *in vivo* biology of lipoxygenases.  
In: Proceedings of the 9th International Conference on Prostaglandins & Related Compounds, 67 June, 1994.

**D.3. Abstracts and Proceedings. (cont.)**

8. Harats, D., Kurihara, H., Belloni, P., Oakley, H., Ziober, A., Cain, G., Kurihara, Y., Lawn, R., Sigal, E. Targeting gene expression to the vascular wall in transgenic mice using the murine preproendothelin-1 promoter  
Circulation 90 (4) Part 2: I-517, 1994.

9. Sigal, E, Kurihara, H., Belloni, P., Cain, G., Lawn, R., Harats, D.  
Targeting gene expression to the vascular wall in transgenic mice using the murine preproendothelin-promoter.  
FASEB, April 1995, IIIA856.

10. Harats, D., Kurihara, H., Belloni, P., Oakley, H., Ziober, A., Cain, G., Kurihara, Y., Lawn, R., Sigal, E.  
Targeting gene expression to the vascular wall and the airway epithelium in transgenic mice using the murine preproendothelin-1 promoter.  
Am. Rev. Resp. Dis. 151:4 A 672. 1995.

11. Harats, D., Kurihara, H., Belloni, P., Lawn, R., Sigal, E.  
Using the murine preproendothelin-1 promoter to target gene expression to the vascular wall.  
Atherosclerosis, 115/suppl S41, June, 1995.

12. Harats, D., Tomlanovich, SJ, Conte, Jr JE, Golden, JA.  
Aerosolized pentamidine prophylaxis for *Pneumocystis Carinii Pneumonia* in solid organ transplantation: Preliminary observation.  
In: Proceedings of The 35th ICAAC, (331) September 1995.

13. Sigal, E., Kurihara, H., Belloni, P., Cain, G., Lawn, R., Harats, D.  
Targeting gene expression to the vascular wall in transgenic mice using the murine preproendothelin-1 promoter.  
In the proceedings of the 64th European Atherosclerosis Society, Utrecht, Netherlands, S41, 1995.

14. Harats, D., Kurihara, H., Lawn, R., Sigal, E.  
Targeting gene expression to the vascular wall in transgenic mice using the murine preproendothelin-1 promoter.  
In: Proceedings of The 12th Inter. Symp. on Drug Affecting Lipid Metabolism, 67; 1995.

15. Harats, D., Sigal, E.  
Targeting gene expression to the vascular wall in transgenic mice the murine prepromoter.  
In: Proceedings of The Israel Society for Arteriosclerosis Research. Tel Aviv, Israel, December 1995.

**D.3. Abstracts and Proceedings. (cont.)**

16. Harats, D., Kurihara, H., Levkovitz., Sigal, E.

15-Lipoxygenase overexpression induces atherosclerosis in LDL deficient mice.

The 66th Annual Meeting of the European Atherosclerosis Society, Florence, Italy  
Atherosclerosis, July 1996.

17. Harats, D.,

15-Lipoxygenase overexpression induces atherosclerosis in LDL deficient mice.

In: Proceedings of The Israel Society for Arteriosclerosis Research. Jerusalem, Israel,  
December 1996.

18. Harats, D., Kurihara, H., Levkovitz., Sigal, E.

15-Lipoxygenase overexpression induces atherosclerosis in LDL deficient mice.

In: Proceedings of The Keystone Symposia on Atherosclerosis, 29, 1997.

19. Harats, D., George, J., Afec, A., Gillburd, B., Levkovitz, H., Shaiah, A., Goldberg, I., Kopolovitz, Y., Shoenfeld, Y.

Hyperimmunization of chow fed ApoE deficient mice with homologous oxidized Low Density Lipoprotein suppresses early atherogenesis.

Circulation (134) 18, 1997

20. Harats, D., George, J., Afec, A., Gillburd, B., Blank, M., Goldberg, I., Kopolovitz, Y., Wick, G., Shoenfeld, Y.

Accelerated Early Atherogenesis in C57BL/6J Mice Immunized With Mycobacterium Tuberculosis.

Circulation (134) 34, 1997.

21. Harats, D., Kurihara, H., Levkovitz, H., Shaish, A., Sigal, E.

15-Lipoxygenase overexpression induces atherosclerosis in LDL -receptor deficient mice.

Circulation (134) 279, 1997.

22. Harats, D., Shaish, A., George, J., Afec, A., Gillburd, B., Kopolovitz, Y., Shoenfeld, Y.

Induction of early atherosclerosis in LDL-receptor deficient mice immunized with beta 2 GPI.

Circulation (134) 40-39, 1997.

23. Harats, D., Kurihara, H., Shaish, A., Sigal, E.

15-Lipoxygenase overexpression induces atherosclerosis in LDL -receptor deficient mice.

Circulation, (96) 8: I 167, 1997.

**D.3. Abstracts and Proceedings. (cont.)**

24. Harats, D., Shaish, A., George, J., Afec, A., Gillburd, B., Kopolovitz, Y., Shoenfeld, Y.

Induction of early atherosclerosis in LDL-receptor deficient mice immunized with beta 2 glycoprotein I.

Circulation, (96) 8: 1110, 1997.

25. Ehrenfeld, M., Harats, D.

Serum lipoprotein(a) level in patients with systemic lupus erythematosus.

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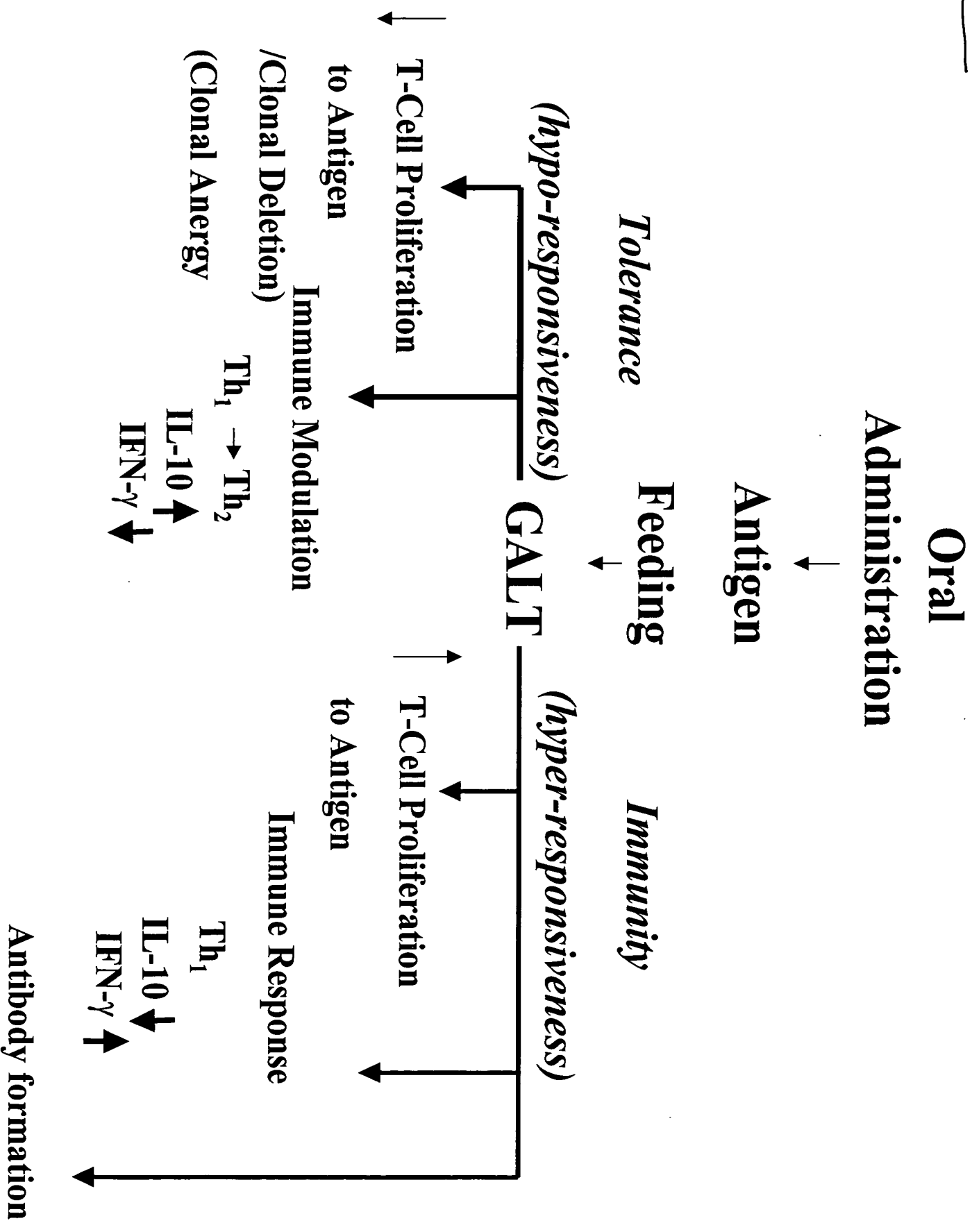
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PANEL II

ORAL  
TOLERANCE

